Appendix A. Search Strategy

DATABASE SEARCHED & TIME PERIOD COVERED:
PubMed - ~1946 - 4/20/2014

SEARCH STRATEGY:
gout OR gouty
AND
X-ray* OR radiograph* OR erosion OR diagnostic imaging[mh] OR radiography [Subheading] OR Computed tomography OR Computer tomography OR dual energy CT OR DECT OR Radiography, Dual-Energy Scanned Projection[mh] OR Ultrasound OR Ultrasonography[mh] OR Ultrasonography[sh] OR double contour OR radionuclide imaging [Subheading] OR (polariz* AND microscop*) OR Joint aspiration OR Serum urate OR Uric acid OR Crystal* OR Tophi OR tophus OR tophaceous OR Synovial fluid OR Urate OR kidney stones OR Kidney Calculi[mh] OR urate stones OR gouty nephropathy OR Hyperuricemia OR clinical symptom*
AND
Accura* OR Sensitivity and specificity[mh] OR Sensitivity[tiab] OR Specificity[tiab] OR False positive reactions[mh] OR false positive* OR False negative reactions[mh] OR False negative* OR Predictive value OR predictive value of tests[mh] OR Distinguish* OR Differential* OR Identif* OR Detect* OR valid* OR reliab* OR reproducibility of results

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DATABASE SEARCHED & TIME PERIOD COVERED:
Web of Science SCI-EXPANDED, SSCI, A&HCI, CPCI-S, CPCI-SSH – 1/1/1980 - 4/21/2014

SEARCH STRATEGY:
ts=(gout OR gouty)
AND
ts=(x-ray* or radiograph* or erosion or diagnostic imaging or Computed tomography or Computer tomography or dual energy CT or DECT or Ultrasound or Ultrasonograph* or double contour or radionuclide or (polariz* and microscop*) or Joint aspiration or Serum urate or Uric acid or Crystal* or Tophi or tophus or tophaceous or Synovial fluid or Urate or kidney stones or Kidney Calculi or urate stones or gouty nephropathy or Hyperuricemia or clinical symptom*)
AND
ts=(Accura* or Sensitivity or Specificity or false positive* or False negative* or Predictive value or Distinguish* or Differential* or Identif* or Detect* or valid* or reliab* or reproducibility of results)

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DATABASE SEARCHED & TIME PERIOD COVERED:
Cochrane – Earliest - 4/21/2014

SEARCH STRATEGY:
gout or gouty
AND
x-ray* or radiograph* or erosion or diagnostic imaging or Computed tomography or Computer tomography or dual energy CT or DECT or Ultrasound or Ultrasonograph* or double contour or radionuclide or (polariz* and microscop*) or Joint aspiration or Serum urate or Uric acid or Crystal* or

Tophi or tophus or tophaceous or Synovial fluid or Urate or kidney stones or Kidney Calculi or urate stones or gouty nephropathy or Hyperuricemia or clinical symptom* IN TITLE, ABSTRACT, KEYWORD
AND
Accura* or Sensitivity or Specificity or false positive* or False negative* or Predictive value or Distinguish* or Differential* or Identif* or Detect* or valid* or reliab* or reproducibility of results

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DATABASE SEARCHED & TIME PERIOD COVERED:
Embase 1/1/1972-present

LIMITERS:
Humans

SEARCH STRATEGY:
'gout' OR 'gout'/exp OR gout OR gouty
AND
'x ray'/exp OR 'x ray' OR 'x rays'/exp OR 'x rays' OR 'x-ray'/exp OR 'x-ray' OR 'x-rays'/exp OR 'x-rays' OR radiograph* OR 'erosion'/exp OR erosion OR 'diagnostic imaging'/exp OR 'diagnostic imaging' OR 'computed tomography'/exp OR 'computed tomography' OR 'computer tomography'/exp OR 'computer tomography' OR 'dual energy ct' OR dect OR 'ultrasound'/exp OR ultrasound OR ultrasonograph* OR 'double contour' OR 'radionuclide'/exp OR radionuclide OR microscop* OR 'joint aspiration'/exp OR 'joint aspiration' OR 'serum urate'/exp OR 'serum urate' OR 'uric acid'/exp OR 'uric acid' OR crystal* OR tophi OR tophus OR tophaceous OR 'synovial fluid'/exp OR 'synovial fluid' OR 'urate'/exp OR urate OR ('kidney'/exp OR kidney AND stones) OR ('kidney'/exp OR kidney AND ('calculi'/exp OR calculi)) OR 'urate stones'/exp OR 'urate stones' OR 'gouty nephropathy' OR 'hyperuricemia'/exp OR hyperuricemia OR 'hyperuricaemia'/exp OR hyperuricaemia OR 'clinical symptom' OR 'clinical symptoms'
AND
accura* OR sensitivity OR specificity OR 'false positive' OR 'false positives' OR 'false negative' OR 'false negatives' OR 'predictive value'/exp OR 'predictive value' OR distinguish* OR differential* OR identif* OR detect* OR valid* OR reliab* OR 'reproducibility of results'/exp OR 'reproducibility of results'

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DATABASE SEARCHED & TIME PERIOD COVERED:
Web of Science – 1/1/2006-4/25/2014

SEARCH STRATEGY:
Forward search on the following article:
EULAR evidence based recommendations for gout. Part I: Diagnosis. Report of a task force of the standing committee for international clinical studies including therapeutics (ESCISIT)
W Zhang, M Doherty, E Pascual, T Bardin, V Barskova, P Conaghan, J Gerster, J Jacobs, B Leeb, F Liote´, G McCarthy, P Netter, G Nuki, F Perez-Ruiz, A Pignone, J Pimenta˜o, L Punzi, E Roddy, T Uhlig, I Zimmermann-Go` rska
Ann Rheum Dis 2006;65:1301–1311. doi: 10.1136/ard.2006.055251

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DATABASE SEARCHED & TIME PERIOD COVERED:
SCOPUS – 1/1/2006-3/19/2014

SEARCH STRATEGY:
Forward search on the following article:
EULAR evidence based recommendations for gout. Part I: Diagnosis. Report of a task force of the standing committee for international clinical studies including therapeutics (ESCISIT)
W Zhang, M Doherty, E Pascual, T Bardin, V Barskova, P Conaghan, J Gerster, J Jacobs, B Leeb, F Liote´, G McCarthy, P Netter, G Nuki, F Perez-Ruiz, A Pignone, J Pimenta˜o, L Punzi, E Roddy, T Uhlig, I Zimmermann-Go` rska
Ann Rheum Dis 2006;65:1301–1311. doi: 10.1136/ard.2006.055251

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DATABASE SEARCHED & TIME PERIOD COVERED:
Grey Literature Report – no date limitation

SEARCH STRATEGY:
Gout OR gouty

NUMBER OF RESULTS: 0

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DATABASE SEARCHED & TIME PERIOD COVERED:
Embase (rerun of 4/22/2014 search) – 1/1/1972-8/13/2014

LIMITERS:
Humans

SEARCH STRATEGY:
'gout' OR 'gout'/exp OR gout OR gouty
AND
'x ray'/exp OR 'x ray' OR 'x rays'/exp OR 'x rays' OR 'x-ray'/exp OR 'x-ray' OR 'x-rays'/exp OR 'x-rays' OR radiograph* OR 'erosion'/exp OR erosion OR 'diagnostic imaging'/exp OR 'diagnostic imaging' OR 'computed tomography'/exp OR 'computed tomography' OR 'computer tomography'/exp OR 'computer tomography' OR 'dual energy ct' OR dect OR 'ultrasound'/exp OR ultrasound OR ultrasonograph* OR 'double contour' OR 'radionuclide'/exp OR radionuclide OR microscop* OR 'joint aspiration'/exp OR 'joint aspiration' OR 'serum urate'/exp OR 'serum urate' OR 'uric acid'/exp OR 'uric acid' OR crystal* OR tophi OR tophus OR tophaceous OR 'synovial fluid'/exp OR 'synovial fluid' OR 'urate'/exp OR urate OR ('kidney'/exp OR kidney AND stones) OR ('kidney'/exp OR kidney AND ('calculi'/exp OR calculi)) OR 'urate stones'/exp OR 'urate stones' OR 'gouty nephropathy' OR 'hyperuricemia'/exp OR hyperuricemia OR 'hyperuricaemia'/exp OR hyperuricaemia OR 'clinical symptom' OR 'clinical symptoms'
AND
accura* OR sensitivity OR specificity OR 'false positive' OR 'false positives' OR 'false negative' OR 'false negatives' OR 'predictive value'/exp OR 'predictive value' OR distinguish* OR differential* OR identif* OR detect* OR valid* OR reliab* OR 'reproducibility of results'/exp OR 'reproducibility of results'

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CLINICALTRIALS.GOV

CONDITION = "Gout"
RECEIVED FROM: Earliest in database to 5/6//2014

Appendix B. List of Excluded Studies

Not Human – N=1

1. Sundaram PV, Igloi MP, Wassermann R, et al. Immobilized-enzyme nylon-tube reactor for routine determination of uric acid in serum. Clin Chem. 1978 Oct;24(10):1813-7. PMID: 699291.

Diagnostic Method beyond scope of review- N=44

1. Backhaus M, Schmidt WA, Mellerowicz H, et al. [Technical aspects and value of arthrosonography in rheumatologic diagnosis. 4: Ultrasound of the elbow]. Z Rheumatol. 2002 Aug;61(4):415-25. PMID: 12426847.

2. Barber C, Thompson K, Hanly JG. Impact of a rheumatology consultation service on the diagnostic accuracy and management of gout in hospitalized patients. J Rheumatol. 2009 Aug;36(8):1699-704. PMID: 19567626.

3. Chauhan N, Pundir CS. An amperometric uric acid biosensor based on multiwalled carbon nanotube-gold nanoparticle composite. Anal Biochem. 2011 Jun 15;413(2):97-103. PMID: 21315682.

4. Cheng X, Haggins DG, York RH, et al. Analysis of crystals leading to joint arthropathies by Raman spectroscopy: comparison with compensated polarized imaging. Appl Spectrosc. 2009 Apr;63(4):381-6. PMID: 19366502.

5. Chu QC, Lin M, Geng CH, et al. Determination of uric acid in human saliva and urine using miniaturized capillary electrophoresis with amperometric detection. Chromatographia. 2007 Feb;65(3-4):179-84. PMID: WOS:000244670700007.

6. Dodd LG, Major NM. Fine-needle aspiration cytology of articular and periarticular lesions. Cancer. 2002 Jun 25;96(3):157-65. PMID: 12115304.

7. Friedman RJ, Hawthorne KB, Genez BM. The use of computerized tomography in the measurement of glenoid version. J Bone Joint Surg Am. 1992 Aug;74(7):1032-7. PMID: 1522089.

8. Galvez J, Saiz E, Linares LF, et al. Delayed examination of synovial fluid by ordinary and polarised light microscopy to detect and identify crystals. Ann Rheum Dis. 2002 May;61(5):444-7. PMID: 11959769.

9. Goldenberg DL, Cohen AS. Synovial membrane histopathology in the differential diagnosis of rheumatoid arthritis, gout, pseudogout, systemic lupus erythematosus, infectious arthritis and degenerative joint disease. Medicine (Baltimore). 1978 May;57(3):239-52. PMID: 642792.

10. Heidelmann G, Thiele P, Crasselt C, et al. [Uncharacteristic symptoms of the motor apparatus in gout]. Z Rheumatol. 1975 Nov-Dec;34(11-12):381-90. PMID: 1210793.

11. Hujazi I, Ambler G, Arora A, et al. Role of Newman's classification in predicting outcomes in patients with crystal arthritis. International Orthopaedics. 2012 Jun;36(6):1287-90. PMID: WOS:000304160000027.

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13. Johnson JS, Freemont AJ. A 10 year retrospective comparison of the diagnostic usefulness of synovial fluid and synovial biopsy examination. Journal of Clinical Pathology. 2001;54(8):605-7.

14. Kaneko K, Maru M. Determination of urate crystal formation using flow cytometry and microarea X-ray diffractometry. Anal Biochem. 2000 May 15;281(1):9-14. PMID: 10847604.

15. Klaus R, Fischer W, Hauck HE. Qualitative and Quantitative-Analysis of Uric-Acid, Creatine and Creatinine Together with Carbohydrates in Biological-Material by Hptlc. Chromatographia. 1991 Oct;32(7-8):307-16. PMID: WOS:A1991GP25100001.

16. Koski JM, Hermunen HS, Kilponen VM, et al. Verification of palpation-guided intra-articular injections using glucocorticoid-air-saline mixture and ultrasound imaging (GAS-graphy). Clinical and Experimental Rheumatology. 2006;24(3):247-52.

17. Kratky G, Hefel P. [Differential diagnosis of knee joint fluid. Enzymatic analysis (author's transl)]. Arch Orthop Trauma Surg. 1978 Dec 12;93(1):65-73. PMID: 727932.

18. Lenz W, Klein W, Huth F. [Needle biopsy in gout and pseudogout (author's transl)]. Beitr Pathol. 1976 Apr;157(2):161-82. PMID: 179523.

19. Li X, Wang X, Yu Y, et al. Value of dual energy spectral CT for detecting uric acid deposition in tophaceous gout with base material mapping. Chinese Journal of Radiology (China). 2014;48(4):303-7.

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21. Lin J, Zhao GQ, Che CY, et al. Characteristics of ocular abnormalities in gout patients. Int J Ophthalmol. 2013;6(3):307-11. PMID: 23826523.

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23. Liu Y, Yu P, Sun X, et al. Metabolite target analysis of human urine combined with pattern recognition techniques for the study of symptomatic gout. Mol Biosyst. 2012 Nov;8(11):2956-63. PMID: 22932763.

24. Matsubara C, Yokoi Y, Nakamichi N, et al. [Spectrophotometric determination of uric acid in serum using a titanium (IV)-porphyrin complex]. Yakugaku Zasshi. 1994 Jan;114(1):48-53. PMID: 8133459.

25. McGill NW, McGill VG. Quality assurance for synovial fluid examination for crystals: an improved method. Ann Rheum Dis. 1997 Aug;56(8):504-6. PMID: 9306876.

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29. Papanicolas LE, Hakendorf P, Gordon DL. Concomitant Septic Arthritis in Crystal Monoarthritis. Journal of Rheumatology. 2012 Jan;39(1):157-60. PMID: WOS:000299400500028.

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32. Pobirci O, Bogdan F, Pobirci DD, et al. The study of synovities with articular inflammatory liquid, through clinical-statistical, histological and immunohistochemical methods. Rom J Morphol Embryol. 2011;52(1 Suppl):333-8. PMID: 21424072.

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34. Shidham V, Chivukula M, Basir Z, et al. Evaluation of crystals in formalin-fixed, paraffin-embedded tissue sections for the differential diagnosis of pseudogout, gout, and tumoral calcinosis. Mod Pathol. 2001 Aug;14(8):806-10. PMID: 11504841.

35. Sivera F, Aragon R, Pascual E. First metatarsophalangeal joint aspiration using a 29-gauge needle. Ann Rheum Dis. 2008 Feb;67(2):273-5. PMID: 17557892.

36. Song JS, Choi ST, Park EH. The usefulness of procalcitonin for differentiating acute gout arthritis from infectious disease. Annals of the Rheumatic Diseases. 2014;73.

37. Strobel G, Schwarz R, Heppt P, et al. [Use of an improved transmission ultrasound camera for diagnosis of rheumatic joint diseases]. Z Rheumatol. 1993 Mar-Apr;52(2):114-20. PMID: 8517073.

38. Vasil'ev A, Obramenko IE. [Magnetic resonance imaging differential diagnosis of psoriatic polyarthropathy with gouty polyarthropathy and rheumatoid polyarthritis]. Vestn Rentgenol Radiol. 2013 Jan-Feb(1):29-33. PMID: 23700923.

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Not gout diagnosis or management - N=69

1. Antommattei O, Schumacher HR, Reginato AJ, et al. Prospective study of morphology and phagocytosis of synovial fluid monosodium urate crystals in gouty arthritis. J Rheumatol. 1984 Dec;11(6):741-4. PMID: 6520827.

2. Artmann A, Ratzenbock M, Noszian I, et al. [Dual energy CT--a new perspective in the diagnosis of gout]. Rofo. 2010 Mar;182(3):261-6. PMID: 19862652.

3. Bardin T. Epidemiology of gout. Épidémiologie de la goutte. 2007;74(2):147-9.

4. Blaauw AAM, Schuwirth LWT, Vandervleuten CPM, et al. Assessing Clinical Competence - Recognition of Case Descriptions of Rheumatic Diseases by General-Practitioners. British Journal of Rheumatology. 1995 Apr;34(4):375-9. PMID: WOS:A1995RC64700016.

5. Choi HK, Burns LC, Shojania K, et al. Dual energy CT in gout: a prospective validation study. Ann Rheum Dis. 2012 Sep;71(9):1466-71. PMID: 22387729.

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10. Dixit AK, Dey RK, Panda AK, et al. Biochemical and serological profiling of sandhi shoola (Arthralgia) patients of ayurveda hospital. International Journal of Research in Ayurveda and Pharmacy. 2013 March/April;4(2):141-4. PMID: 2013400880 FULL TEXT LINK http://dx.doi.org/10.7897/2277-4343.04210.

11. Eid AS, Burrows V, Murray JRM, et al. Are we managing acute knee effusion well? British Journal of Medical Practitioners. 2012;5(1)PMID: 2012260180.

12. Fernandes EA, Lopes MG, Mitraud SA, et al. Ultrasound characteristics of gouty tophi in the olecranon bursa and evaluation of their reproducibility. Eur J Radiol. 2012 Feb;81(2):317-23. PMID: 21237599.

13. Feydy A, Liote F, Carlier R, et al. Cervical spine and crystal-associated diseases: imaging findings. Eur Radiol. 2006 Feb;16(2):459-68. PMID: 15856241.

14. Fiechtner JJ, Simkin PA. Urate spherulites in gouty synovia. JAMA. 1981 Apr 17;245(15):1533-6. PMID: 7206161.

15. Filippucci E, Delle Sedie A, Riente L, et al. Ultrasound imaging for the rheumatologist. XLVII. Ultrasound of the shoulder in patients with gout and calcium pyrophosphate deposition disease. Clin Exp Rheumatol. 2013 Sep-Oct;31(5):659-64. PMID: 24050142.

16. Filippucci E, Scire CA, Delle Sedie A, et al. Ultrasound imaging for the rheumatologist. XXV. Sonographic assessment of the knee in patients with gout and calcium pyrophosphate deposition disease. Clin Exp Rheumatol. 2010 Jan-Feb;28(1):2-5. PMID: 20346230.

17. Gaber W, Ezzat Y, Abd El Rahman SF. Role of diagnostic ultrasonography in detecting gouty arthritis. Egyptian Rheumatologist. 2013 April;35(2):71-5. PMID: 2013171876 FULL TEXT LINK http://dx.doi.org/10.1016/j.ejr.2012.12.003.

18. Gamez-Nava JI, Gonzalez-Lopez L, Davis P, et al. Referral and diagnosis of common rheumatic diseases by primary care physicians. British Journal of Rheumatology. 1998;37(11):1215-9.

19. Gancheva RN, Kundurdjiev A, Ivanova M, et al. Ultrasonographic examination of target organs in gout. Annals of the Rheumatic Diseases. 2014;73.

20. Gordon TP, Bertouch JV, Walsh BR, et al. Monosodium urate crystals in asymptomatic knee joints. J Rheumatol. 1982 Nov-Dec;9(6):967-9. PMID: 7161792.

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22. Gruber M, Bodner G, Rath E, et al. Dual-energy computed tomography compared with ultrasound in the diagnosis of gout. Rheumatology (Oxford). 2014 Jan;53(1):173-9. PMID: 24136065.

23. Guggi V, Calame L, Gerster JC. Contribution of digit joint aspiration to the diagnosis of rheumatic diseases. Joint Bone Spine. 2002;69(1):58-61.

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26. Howard RG, Pillinger MH, Gyftopoulos S, et al. Reproducibility of musculoskeletal ultrasound for determining monosodium urate deposition: concordance between readers. Arthritis Care Res (Hoboken). 2011 Oct;63(10):1456-62. PMID: 21702086.

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36. Liu W, Xue HD, Zeng XJ, et al. [Application of dual-energy computed tomography for detecting uric acid deposition in patients with gout]. Zhongguo Yi Xue Ke Xue Yuan Xue Bao. 2010 Dec;32(6):645-8. PMID: 21219793.

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Appendix C. Evidence Table

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Bongartz et al., 2014[32] Location: North America Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 81 Mean Age: 60.3 [nr] Age Range: NR Percent Female: 42% Mean Duration Current Flare: 6 weeks (about half presented with a first flare of inflammatory arthritis and a symptom duration <6 weeks)	Test(s): DECT Reference Standard: Synovial fluid aspiration and crystal analysis snovial fluid analysis with electron microscopy All receive the reference standard: Yes Clinical Signs and Symptoms: NA	Inclusion Criteria: referral to rheumatology clinic for joint aspiration or injection Exclusion Criteria: tophaceous gout	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives Adverse effects associated with testing Treatment decision resulting from diagnosis Patient Characteristics for Subgroup Analysis: Duration of current episode/flare/symptoms Duration of these kinds of flares Physician: Rheumatologist Radiologists Practitioner: Rheumatologist
Glazebrook et al., 2011[10] Location: North America Site(s) [Num. of Sites]: University rheumatology department[1] radiology dept.[ ]	Number of Patients: 94 Mean Age: 62.3 Age Range: 29-89 Percent Female: 41/94 Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): DECT Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: NA	Inclusion Criteria: clinical suspicion of MSU crystals in affected joint; ordering of DECT; performance of DECT according to protocol between 4/08 and 2/10 Exclusion Criteria: participation in ongoing gout trial;	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives inter-rater reliability Patient Characteristics for Subgroup Analysis: None Physician: Radiologists Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Hasselbacher et al., 1987[43] Location: North America Site(s) [Num. of Sites]: laboratories[26]	Number of Patients: 4 Mean Age: NR Age Range: NR Percent Female: NR Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes	Inclusion Criteria: Not applicable, this is a study of how labs differ in accuracy of detecting crystals Exclusion Criteria: NR	Outcomes: correct diagnosis by lab Patient Characteristics for Subgroup Analysis: Not applicable Physician: Not applicable Practitioner: Technician
Huppertz et al., 2014[33] Location: Europe Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 60 Mean Age: 62 [11.3] Age Range: 36-82 Percent Female: 0.18 Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): DECT Ultrasound Reference Standard: Synovial fluid aspiration and crystal analysis algorithm incorporating a score incorporating serum uric acid level, first MTP joint involvement, gender, previous patient-reported arthritis attack, cardiovascular diseases, joint redness and onset within 1 day All receive the reference standard: Yes Clinical Signs and Symptoms: NA	Inclusion Criteria: patients with suspicion of gout undergoing DECT Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value Patient Characteristics for Subgroup Analysis: None Physician: Rheumatologist Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Janssens et al., 2010[29] Location: Europe Site(s) [Num. of Sites]: Primary care provider's office[NR]	Number of Patients: 328 Mean Age: 58.0±13.5 Age Range: NR Percent Female: 20% Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: ACR criteria. Initial diagnosis cut-off point set at >= 6 (modifying cut-off point did not induce any changes in sensitivity or specificity)	Inclusion Criteria: Patients presenting with a monoarthritis were included if the family physician suspected they had gout Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value Overall fraction correct Patient Characteristics for Subgroup Analysis: Number of positive ACR criteria Physician: Rheumatologist Practitioner: Rheumatologist
Janssens et al., 2010[28] Location: Europe Site(s) [Num. of Sites]: Primary care provider's office[nr] University primary care department[ ]	Number of Patients: 328 Mean Age: 57.7 (13.6) Age Range: NR Percent Female: MSU+:10.5%; MSU-: 37.8% Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: male sex; previous patient-reported arthritis attack; onset within 1 day; joint redness; first MTP involvement; hypertension or 1 or more CVD; SUA>5.88mg/dL (other potential factors tested as well, e.g., other comorbidities and long-term followup)	Inclusion Criteria: diagnosis of gout by family physician Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value The area under the ROC curve/AUC/c-statistic/concordance statistic Patient Characteristics for Subgroup Analysis: None Physician: Family Practice Rheumatologist Practitioner: Rheumatologist

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Kienhorst et al., 2013[24] Location: Europe Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 390 Mean Age: NR Age Range: NR Percent Female: NR Mean Duration Current Flare: NR Mean Duration of Disease: no prior diagnosis	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: male sex; previous patient reported arthritis attack; onset within one day; joint redness; 1st MTP joint involvement; hypertension or one or more CVD, sUA>0.35 mmol/L	Inclusion Criteria: adult patients with signs and symptoms of monoarthritis and possibility of gout referred to a rheumatology clinic by a primary care physician Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The area under the ROC curve/AUC/c-statistic/concordance statistic Patient Characteristics for Subgroup Analysis: None Physician: Rheumatologist Practitioner: Unclear/not specified
Kienhorst et al., 2014[26] Location: Europe Site(s) [Num. of Sites]: Primary care provider's office[93] University rheumatology department[1]	Number of Patients: 159 Mean Age: 58.2[13.8] Age Range: NR Percent Female: 22.6 Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: Need to see reference 2 (probably items listed in Table 1 but unclear if all)	Inclusion Criteria: patients who received probably or possible diagnosis of gout based on clinical signs/symptoms in primary care setting; monoarthritis of the first MTP joint Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value Patient Characteristics for Subgroup Analysis: None Physician: Family Practice Rheumatologist Not specified or unclear Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Lai et al., 2011[36] Location: Asia Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 80 Mean Age: Gout patients: median age 74.0; Nongout patients median age 66.0 Age Range: 52.8-80.8 Percent Female: gout:17.6%; nongout: 52.2% Mean Duration Current Flare: NR Mean Duration of Disease: median: 8 years	Test(s): Ultrasound Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: NA	Inclusion Criteria: having undergone ultrasound guided joint aspiration at the authors' rheumatology division between march 2009 and March 2010 after presenting with mono or oligoarthritis with acute or subacute onset Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value Patient Characteristics for Subgroup Analysis: Another arthropathy Physician: Rheumatologist Practitioner: Unclear/not specified
Lamers-Karnebeek et al., 2014[34] Location: Europe Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 54 Mean Age: 59.0 Age Range: 41.8-69.5 Percent Female: 29.6 Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Ultrasound Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes	Inclusion Criteria: acute onset of mono- or oligoarthritis Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value likelihood ratios and inter-rater reliability for US readings Patient Characteristics for Subgroup Analysis: Another arthropathy US findings e.g., double contour sign, snowflake, tophus Physician: Rheumatologist Not specified or unclear Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Lenski et al., 2014[25] Location: Europe Site(s) [Num. of Sites]: Hospital emergency department[1]	Number of Patients: 82 Mean Age: 72.4 Age Range: 30-96 Percent Female: NR Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Serum UA Reference Standard: Synovial fluid aspiration and crystal analysis cultures for septic arthritis Clinical Signs and Symptoms: The combination of tests was really to differentiate septic from gouty arthritis. The tests included serum UA, WBC, CRP,and synovial glucose,UA, IL-6, LDH, total protein	Inclusion Criteria: patients diagnosed with septic arthritis (by culture) or gouty arthritis (by synovial fluid analysis) Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The area under the ROC curve/AUC/c-statistic/concordance statistic Patient Characteristics for Subgroup Analysis: Another arthropathy synovial fluid lactic acid Physician: Not specified or unclear Practitioner: Technician
Malik et al., 2009[27] Location: North America Site(s) [Num. of Sites]: University rheumatology department[1]	Number of Patients: 82 Mean Age: 64.5 Age Range: NA Percent Female: 6 Mean Duration Current Flare: NA Mean Duration of Disease: NA	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: Crystal analysis vs. three diagnostic signs/symptoms: 1. ACR (ARA) Preliminary Criteria2. New York Criteria3. Rome Criteria	Inclusion Criteria: Synovial fluid aspirated and analyzed at some point. Exclusion Criteria: NA	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value False positivity Patient Characteristics for Subgroup Analysis: Gout criteria Physician: Rheumatologist Not specified or unclear Practitioner: Technician

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Park et al., 2014[44] Location: Asia Site(s) [Num. of Sites]: University hospital departments of rheumatology and laboratory medicine[2]	Number of Patients: 179 Mean Age: 62.6 ± 16.4 (age at diagnosis) Percent Female: 5.6 Mean Duration Current Flare: 3.3 ± 3.5 days	Test(s): Synovial fluid aspiration and crystal analysis Reference Standard: Synovial fluid aspiration and crystal analysis ACR/ARA guidelines All receive the reference standard: Yes	Inclusion Criteria: patients with a diagnosis of gout, who had undergoneSF examination from October 1999 to September 2011 Exclusion Criteria: patients with unclassified acute arthritis, intercritical gout without acute symptoms, pseudogout, osteoarthritis, concomitant septic and gouty arthritis	Outcomes: Treatment decision resulting from diagnosis Misdiagnosis related harms Patient Characteristics for Subgroup Analysis: Duration of current episode/flare/symptoms Type of clinician performing tests Patient age Type 2 diabetes or metabolic syndrome Crystal positive and crystal negative gout Physician: Rheumatologist Practitioner: Technician
Rettenbacher et al., 2008[35] Location: Europe Site(s) [Num. of Sites]: Academic radiology department[1]	Number of Patients: 105 Mean Age: 59 Age Range: 31-89 Percent Female: 12 Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Ultrasound Plain x-ray Reference Standard: Synovial fluid aspiration and crystal analysis characteristic clinical and laboratory findings All receive the reference standard: Yes Clinical Signs and Symptoms: NA	Inclusion Criteria: patients with suspected gout referred from rheumatology clinic Exclusion Criteria: inability to establish a definite diagnosis	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value Physician: Radiologists Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Richette et al., 2014[30] Location: Europe Site(s) [Num. of Sites]: University rheumatology department[14]	Number of Patients: 244 Mean Age: 59.8±12.5 years Age Range: NR Percent Female: 40.5% Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: 11 items Self-reported history of gout Male sex Self-reported history of hyperuricaemiaTophus Hypertriglyceridaemia Cardiovascular disease Pain intensity Involvement of toes, foot or ankles;Treatment with corticosteroids; Treatment with NSAIDs	Inclusion Criteria: gout or other arthritis Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The area under the ROC curve/AUC/c-statistic/concordance statistic Patient Characteristics for Subgroup Analysis: Duration of current episode/flare/symptoms Patient age Patient sex Type 2 diabetes or metabolic syndrome Another arthropathy Current use of medication Physician: Not applicable Practitioner: Unclear/not specified

Author, Year, **Location (continent),** **Type of practice** **care setting(s) [# each]**	**Number of participants,** **Mean age,** **Age range,** **% female,** **Patients have gout at start of study,** **Mean duration of current flare,** **Mean duration of illness**	**Type of diagnostic test,** **Gold standard (reference test),** **Did all patients get the gold standard?** **If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes,** **Patient Characteristics,** **Type of physician,** **Type of practitioner**
Vazquez-Mellado et al., 2012[31] Location: North America Site(s) [Num. of Sites]: University rheumatology department[ ]	Number of Patients: 167 Mean Age: 54[16.8] for gout, 49.6 overall Age Range: NR Percent Female: 24% for gout, 7% for RA, 42% for SA, 10% for OA Mean Duration Current Flare: NR Mean Duration of Disease: NR	Test(s): Some combination of clinical signs, symptoms, and history Reference Standard: Synovial fluid aspiration and crystal analysis All receive the reference standard: Yes Clinical Signs and Symptoms: >1 attack, mono/oligoarthritis, rapid onset of pain and swelling, podagra, erythema, tarsitis, probable tophi, hyperuricemia, and combinations of these items	Inclusion Criteria: For gout, positive synovial fluid MSU crystal analysis Exclusion Criteria: NR	Outcomes: Sensitivity or the number of false negatives Specificity or the number of false positives The positive predictive value The negative predictive value The area under the ROC curve/AUC/c-statistic/concordance statistic likelihood ratios, odds ratio Patient Characteristics for Subgroup Analysis: possibly age, sex, and secondary gout, e.g., gout and comorbidity such as CRF, hematologic condition Physician: Not specified or unclear Practitioner: Unclear/not specified

Author, Year, Location (continent), Type of practice care setting(s) [# each]	**Number of participants, Mean age, Age range, % female, Patients have gout at start of study, Mean duration of current flare, Mean duration of illness**	**Type of diagnostic test, Gold standard (reference test), Did all patients get the gold standard? If diagnostic test was a clinical sign, symptom or a composite of signs and symptoms, what did they include?**	**Inclusion and Exclusion Criteria**	**Outcomes, Patient Characteristics, Type of physician, Type of practitioner**
Wallace et al., 1977[9] Location: North America Site(s) [Num. of Sites]: University rheumatology department [38 (probably some private, also)]	Number of Patients: 706 Mean Age: gout: 56.2; RA: 47.6 Age Range: NR Percent Female: gout: , RA: 64.313.6 Mean Duration Current Flare: NR Mean Duration of Disease: Gout: 10.1 years	Test(s): Some combination of clinical signs, symptoms, and history Synovial fluid aspiration and crystal analysis Reference Standard: clinical opinion inferred Clinical Signs and Symptoms: >1 acute attack; maximum inflammation developed in 1 day; monoarthritis; redness over joint; first MTP painful or swollen; unilateral first MTP joint attack; unilateral tarsal joint attack; tophus (proven or suspected); hyperuricemia; asymmetric swelling within joint on x-ray; subcortical cysts without	Inclusion Criteria: NR Exclusion Criteria: NR	Outcomes: unclear Physician: Rheumatologist Practitioner: Rheumatologist

Table Notes: ACR (ARA)= American College of Rheumatology (American Rheumatology Association); AUC=Area Under the Curve; CRP= C-reactive protein; CS=Corticosteroid; CVD=Cardiovascular disease; DECT=Dual-energy computed tomography; LDH=Lactatdehydrogenase; MSU=monosodium urate; MTP =metatarsophalangeal; NA=Not Applicable; NR=Not reported; NSAIDS=Non-steroidal anti-inflammatory drugs; OA=osteoarthritis; RA=Rheumatoid Arthritis; ROC=receiver-operating characteristics; SA=spondylo-arthropathy, SUA=Serum Uric Acid, UA=Urinalysis, WBC=White blood count

Appendix D. Data Abstraction Tools

1. **Diagnosis of gout data abstraction tool**
2. **QUADAS-2 –Tool for the Quality Assessment of Diagnostic Accuracy Studies**
3. **AMSTAR-Assessment of Reporting Quality for Systematic Reviews**

1. Gout Data Abstraction Tool

1. Do you need another article to complete this form?

- ● Yes
- ● No

Clear Response

2. Did the patient population include only patients already diagnosed or assumed to have gout?

- ● Yes
- ● No
- ● Not reported

Clear Response

3. Diagnostic procedure(s) being tested (check all that apply):

- ☐ DECT
- ☐ Ultrasound
- ☐ Plain x-ray
- ☐ Some combination of clinical signs/symptoms/history
- ☐ Serum UA
- ☐ Synovial fluid aspiration and crystal analysis (check only if some variation on the reference standard and not the standard itself)
- ☐ Other [Specify and STOP]
- ☐ Not reported

4. Location (country)

- ☐ North America
- ☐ Central/South America
- ☐ Europe
- ☐ Asia
- ☐ Australia/New Zealand
- ☐ Other (specify region)

5. Care setting and number of sites (check all that apply)

- ☐ Primary care provider's office
- ☐ Urgent care clinic
- ☐ Hospital emergency department
- ☐ Rheumatologist in private practice
- ☐ University rheumatology department
- ☐ Other [specify]
- ☐ Inpatient hospital/long term care only [STOP]
- ☐ Not reported

6. Number of patients total [specify]

7. Mean age +/- SD [specify]

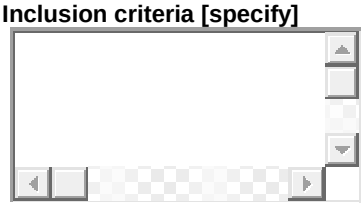
8. Age range _ to _ [specify if given]

9. Percentage of patients who are female:

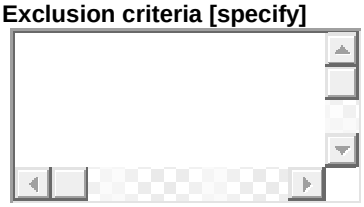
10. Mean duration of current flare episode:

11. Mean duration of disease:

12. Inclusion criteria [specify]



13. Exclusion criteria [specify]



14. If this study measures the validity of a diagnostic test, what is the reference standard:

- ☐ Synovial fluid aspiration and crystal analysis
- ☐ ACR/ARA guidelines
- ☐ Other [specify]
- ☐ Not reported [Exclude, STOP]

15. Did all patients receive the reference standard test?

- ● Yes
- ● No [Exclude]
- ● Unclear [Exclude]

Clear Response

16. Type of physician who performed diagnostic tests: (check all that apply)

- ☐ Family practice
- ☐ General Internist
- ☐ Rheumatologist
- ☐ Emergency physician
- ☐ Not specified or unclear
- ☐ Radiologists
- ☐ Not applicable

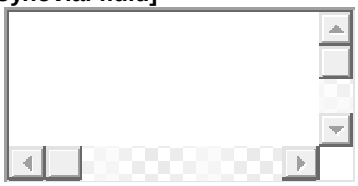
17. Type of practitioner who performed synovial fluid *analysis*:

- ● FP/internist/ED
- ● Rheumatologist

- Technician
- Unclear/not specified
- Not applicable

Clear Response

18. If the diagnostic procedure being tested is a clinical sign or symptom or some combination, what does it [do they] include? [specify; maybe more than one combination or may be comparison of two different signs vs. synovial fluid]



19. Were the findings stratified by any patient characteristics or comorbidities? (check all that apply)

- Duration of current episode/flare/symptoms
- Duration of these kinds of flares (e.g., first time patient vs. previous episodes)
- Type of clinician performing tests
- Type of physician
- Patient age
- Patient sex
- Serum uric acid
- Type 2 diabetes or metabolic syndrome
- Another arthropathy (e.g., osteoarthritis, rheumatoid arthritis)
- Current use of medication (e.g., NSAIDs, steroids, drugs associated with gout flares)
- Other [specify]
- None

20. Study design (select one)

- Prospective
- Retrospective (case control)
- Other [specify]

Clear Response

21. Does the study report (check all that apply):

- Sensitivity or the number of false negatives (people who really have gout but who test negative when the test method is used)
- Specificity or the number of false positives (people who tested negative on the reference standard but who tested positive on the test method)
- The positive predictive value
- The negative predictive value
- The area under the ROC curve/AUC/c-statistic/concordance statistic
- Adverse effects associated with testing
- Pain, inflammation, or quality of life outcomes
- Treatment decision resulting from diagnosis

☐ Other [specify]

☐ None

22. Does this article appear to report on part of a larger study? (select one)

● Yes

● No

Clear Response

23. Does this article cite references we should get?

● Yes

● No

Clear Response

2. QUADAS-2: Tool for the Quality Assessment of Diagnostic Accuracy Studies

Domain 1: Patient Selection

1. Was a consecutive or random sample of patients enrolled?

- Yes
- No
- Unclear
- Not applicable

Clear Response

2. Was a case-control design avoided?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

3. Did the study avoid inappropriate exclusions?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

4. Based on your answers for 1-3, could the selection of patients have introduced bias?
Risk:

- Low
- High
- Unclear
- Not Applicable

Clear Response

Domain 2: Index Test(s) (complete for each index test used)

1. Were the index test results interpreted without knowledge of the reference standard?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

2. If a threshold was used, was it pre-specified?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

3. Based on your answers for 1-2, could the conduct or interpretation of the index test have introduced bias?
Risk:

- Low
- High
- Unclear
- Not Applicable

Clear Response

Domain 3: Reference Standard

1. Is the reference standard likely to correctly classify the target condition?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

2. Were the reference standard results interpreted without knowledge of the results of the index test?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

3. Based on your answers for 1-2, could the reference standard, its conduct, or its interpretation have introduced bias? Risk:

- Low
- High
- Unclear
- Not Applicable

Clear Response

Domain 4: Flow and Timing

1. Was there an appropriate interval between index test(s) and reference standard?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

2. Did all patients receive a reference standard?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

3. Did all patients receive the same reference standard?

- Yes
- No
- Unclear

- Not Applicable

Clear Response

4. Were all patients included in the analysis?

- Yes
- No
- Unclear
- Not Applicable

Clear Response

5. Based on your answers for 1-4, could the patient flow have introduced bias? Risk:

- Low
- High
- Unclear
- Not Applicable

Clear Response

3. AMSTAR Assessment of Reporting Quality for Systematic Reviews

1. Was an 'a priori' design provided?
The research question and inclusion criteria should be established before the conduct of the review.

Note: Need to refer to a protocol, ethics approval, or pre-determined/a priori published research objectives to score a “yes.”
□ Yes
□ No
□ Can't answer
□ Not applicable

2. Was there duplicate study selection and data extraction?
There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.

Note: 2 people do study selection, 2 people do data extraction, consensus process or one person checks the other’s work.
□ Yes
□ No
□ Can't answer
□ Not applicable

3. Was a comprehensive literature search performed?
At least two electronic sources should be searched. The report must include years and databases used (e.g., Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.

Note: If at least 2 sources + one supplementary strategy used, select “yes” (Cochrane register/Central counts as 2 sources; a grey literature search counts as supplementary).
□ Yes
□ No
□ Can't answer
□ Not applicable

4. Was the status of publication (i.e. grey literature) used as an inclusion criterion?
The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.

Note: If review indicates that there was a search for “grey literature” or “unpublished

literature," indicate "yes." SIGLE database, dissertations, conference proceedings, and trial registries are all considered grey for this purpose. If searching a source that contains both grey and non-grey, must specify that they were searching for grey/unpublished lit.
□ Yes
□ No
□ Can't answer
□ Not applicable

5. Was a list of studies (included and excluded) provided?
A list of included and excluded studies should be provided.

Note: Acceptable if the excluded studies are referenced. If there is an electronic link to the list but the link is dead, select "no."
□ Yes
□ No
□ Can't answer
□ Not applicable

6. Were the characteristics of the included studies provided?
In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g., age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.

Note: Acceptable if not in table format as long as they are described as above.
□ Yes
□ No
□ Can't answer
□ Not applicable
7. Was the scientific quality of the included studies assessed and documented?
'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.

Note: Can include use of a quality scoring tool or checklist, e.g., Jadad scale, risk of bias, sensitivity analysis, etc., or a description of quality items, with some kind of result for EACH study ("low" or "high" is fine, as long as it is clear which studies scored "low" and which scored "high"; a summary score/range for all studies is not acceptable).

□ Yes
□ No
□ Can't answer
□ Not applicable

8. Was the scientific quality of the included studies used appropriately in

formulating conclusions?
The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.

Note: Might say something such as “the results should be interpreted with caution due to poor quality of included studies.” Cannot score “yes” for this question if scored “no” for question 7.
□ Yes
□ No
□ Can't answer
□ Not applicable

9. Were the methods used to combine the findings of studies appropriate?
For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e., Chi-squared test for homogeneity, I2
). If heterogeneity
exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e., is it sensible to combine?).

Note: Indicate “yes” if they mention or describe heterogeneity, i.e., if they explain that they cannot pool because of heterogeneity/variability between interventions.
□ Yes
□ No
□ Can't answer
□ Not applicable

10. Was the likelihood of publication bias assessed?
An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test, Hedges-Olken).

Note: If no test values or funnel plot included, score “no”. Score “yes” if mentions that publication bias could not be assessed because there were fewer than 10 included studies.
□ Yes
□ No
□ Can't answer
□ Not applicable

11. Was the conflict of interest included?
Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.

Note: To get a “yes,” must indicate source of funding or support for the systematic review AND for each of the included studies.

□ Yes
□ No
□ Can't answer
□ Not applicable

Shea et al. BMC Medical Research Methodology 2007 7:10 doi:10.1186/1471-2288-7-10

Additional notes (in italics) made by Michelle Weir, Julia Worswick, and Carolyn Wayne based on conversations with
Bev Shea and/or Jeremy Grimshaw in June and October 2008 and July and September 2010.